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UK Study of magnetic resonance imaging (MRI) for breast screening

Submission date	Recruitment status	[_] Prospectively registered
18/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/11/2015	Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.icr.ac.uk/cmagres/maribs/maribs.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

850; G9600413

Study information

Scientific Title
National multicentre study of magnetic resonance imaging (MRI) as a method of screening for breast cancer in women at genetic risk

Acronym
MARIBS

Study objectives
This is a national multicentre study of magnetic resonance imaging (MRI) as a method of screening for breast cancer in women at genetic risk. The study was developed in response to an invitation from the MRC in the UK to address Priority L of the NHS R and D Priorities in Cancer. The sensitivity and specificity of contrast enhanced MRI will be compared with two-view X-ray mammography in a comparative trial.

Approximately 500 women below the age of 50 at high genetic risk of breast cancer will be recruited per year for three years, with annual MRI and X-ray examination continuing for up to five years. A symptomatic cohort will be measured in the first year to establish common criteria for scoring and to ensure consistent practice. Women will be followed up to ascertain the true rate of breast cancer. The MRI examination will comprise an initial high sensitivity screening measurement, followed by a high specificity dynamic measurement in equivocal cases.

In addition to morphological assessment, the kinetics of contrast agent uptake will be measured, and quantitative pharmacokinetic parameters will be derived, to allow the most specific indicators of malignancy to be identified for subsequent routine use. Mammography, localisation, pathology and cytology will be performed in accordance with the NHS Breast Screening Programme quality assurance standards. Similar standards of quality assurance will be applied for MRI measurements and evaluation. The psychological impact and health economics of screening with both modalities in this high-risk group will be ascertained.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Thames Multi-centre Research Ethics Committee approved on the 11th November 1998 (ref: MREC/98/2/38)

Study design
Multicentre non-randomised observational screening genetic epidemiology study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)

Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions
A symptomatic cohort will be measured in the first year to establish common criteria for scoring and to ensure consistent practice. Women will be followed up to ascertain the true rate of breast cancer. The MRI examination will comprise an initial high sensitivity screening measurement, followed by a high specificity dynamic measurement in equivocal cases. In addition to morphological assessment, the kinetics of contrast agent uptake will be measured, and quantitative pharmacokinetic parameters will be derived.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Annual MRI and x-ray breast examination

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/1997

Completion date
31/03/2003

Eligibility

Key inclusion criteria
Group 1:
1. Women aged 35 - 49 years
2. Tested BRCA1 or BRCA2 carriers
3. Known mutation in first degree relative
4. Family history of breast and ovarian cancer (four or more relatives)

Group 2:
1. Women aged 25 - 49 years
2. Tested p53 carriers

3. Known mutation in a first degree relative
4. Family history consistent with Li Frameni syndrome

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Planned sample size: 900

Key exclusion criteria
1. Previous breast cancer (including ductal carcinoma in situ [DCIS])
2. Terminal illness, or life expectancy of less than 5 years
3. Pregnancy or breast-feeding (recruitment suspended until breast-feeding has finished)
4. Current chemotherapy (recruitment suspended until 6 months after treatment ceases; exclusion 2, above, still applies)

Date of first enrolment
01/04/1997

Date of final enrolment
31/03/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Section of Magnetic Resonance
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
222 Euston Road
London
United Kingdom
NW1 2DA

Sponsor type
Research council

Website
http://www.mrc.ac.uk/index.htm

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: G9600413)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015		Yes	No